

REMARKS

Applicants thank the Examiner for the telephonic interviews of November 22, 2004, and January 12, 2005, during which the form and language of the present claims were discussed. Applicants note that the Examiner has not provided Interview Summaries for those interviews. Applicants respectfully request that documentation for the purpose of completing the record.

In the present application Claims 1, 5, 18, 20, and 46 are currently pending. The Examiner indicated in the Advisory Action issued January 13, 2005, that:

The allowable subject matter is a DNA variant of SEQ ID NO:3, wherein said variant is SEQ ID NO:3 comprises at least one variation selected from the group consisting of a T at nucleotide base number 4121 of SEQ ID NO:3; a C at nucleotide base number 4621 of SEQ ID NO:3; a T at nucleotide base number 4970 of SEQ ID NO:3; a C at nucleotide base number 11056 of SEQ ID NO:3; and a T at nucleotide base number 12145 of SEQ ID NO:3, a vector and an isolated host cell comprising said DNA variant.

While Applicants are thankful for the indication of allowable subject material, Applicants must nevertheless request clarification of the above passage. Particularly, the phrasing of "DNA variant of SEQ ID NO:3" is not and has not been recited in the pending claims. Moreover, while the subject material recited in the above passage seems to bear some similarity to the presently-pending claims, no pending claim contains the limitations listed in that passage. Applicants wish to confirm what the Examiner understands to be allowable subject material. Further, Applicants request clarification of the phrase "...a DNA variant is SEQ ID NO:3 comprises at least one variation...." Regardless of what allowable subject material the Examiner may believe to be contained in the present claims, the outstanding

rejections and objections of record are recited in the final Office Action dated September 22, 2004 and in the Advisory Action dated January 13, 2005. Those issues will be addressed hereinbelow.

The Examiner has rejected Claims 1, 5, 8, 18, 20, and 46 under 35 U.S.C. § 112, ¶1 as failing to satisfy the written description requirement. Specifically, the Examiner argues that SEQ ID NO:3 and “contiguous portions thereof” refers to contiguous portions of SEQ ID NO:3 as well as sequences either 5’ or 3’ to the SEQ ID NO:3 since SEQ ID NO:3 is genomic DNA.” (Office Action dated September 22, 2004.) The Examiner further states that, “[t]he ‘contiguous portion’ was interpreted as DNA regions adjacent to 5’ or 3’ of SEQ ID NO:3.” (Advisory Action dated January 13, 2005.) As detailed below, in contrast to the assertions of the Examiner “contiguous portions thereof” or “fragments of SEQ ID NO:3” both mean fragments of SEQ ID NO:3.

As the Applicants have argued in a previous response, “contiguous portions thereof” does not and cannot be interpreted as DNA regions adjacent to 5’ or 3’ of SEQ ID NO:3. As such, “contiguous portions thereof” means only continuous fragments of SEQ ID NO:3 – not fragments outside of or adjacent to SEQ ID NO:3. By the very words themselves, fragments of SEQ ID NO:3 are made up of **portions of SEQ ID NO:3** and not DNA in addition to SEQ ID NO:3. Therefore, the Examiner’s contention that “contiguous portions thereof” means genomic DNA adjacent to SEQ ID NO:3 is untenable.

The present amendment of “contiguous portions thereof” to “fragments of SEQ ID NO:3” does not, in any manner, change the scope of that element of the presently-pending claims. The Examiner has stated that the present amendment changes the scope of the claims. Specifically, the Examiner states:

The claim is now drawn to any DNA sequence that comprises the full length or "a fragment" of SEQ ID NO:3. The claim is previously drawn to a DNA sequence comprises full length SEQ ID NO:3 with the claimed variation, or contiguous portion of SEQ ID NO:3. The "contiguous portion" was interpreted as DNA regions adjacent to 5' or 3' of SEQ ID NO:3. As such **the amendment changes the scope of the claim.** Therefore, a new search is required. (Emphasis added.)

The present amendment absolutely does not change the scope of that claim limitation. As argued above, the phrase "SEQ ID NO:3 and fragments of SEQ ID NO:3" has an equivalent meaning to "SEQ ID NO:3 and contiguous portions thereof." The meaning of the claim terms has not changed; rather the Examiner has finally accepted the Applicants' position. However, during the telephonic interview of November 22, 2004, the Examiner indicated that the phrasing "fragments of SEQ ID NO:3" was more acceptable. Accordingly - and solely to promote prosecution of the present application, Applicants presently amend the claim language to "fragments of SEQ ID NO:3."

The Examiner further argues that if the fragment of SEQ ID NO:3 was limited to SEQ ID NO:3, then the specification fails to meet the written description requirement because the structural and functional relationship of the fragment is not described in the specification. Applicants strenuously disagree with that position of the Examiner. The written description requirement does not require that Applicants disclose the structural and functional relationship of a fragment of DNA. Rather, Applicants can properly satisfy the written description requirement by providing support for the claimed subject material. *See, e.g., Fed. Reg. 66(4) 1099, 1105. (2001).* ("The analysis of whether the specification complies with the written description requirement calls for the examiner to compare the scope of the claim with the scope of the description to determine whether applicant has demonstrated possession of the claimed invention.") Indeed, the written description

requirement for DNA can be satisfied (among other ways) by the explicit listing of the sequence of the claimed DNA fragment. *See Regents of the University of California v. Eli Lilly Co.*, 119 F.3d 1559, at 1566 (Fed. Cir. 1997) (“An adequate written description of a DNA ... requires a precise definition, **such as** by structure, **formula**, chemical name, or physical properties.” (Emphasis added. internal quotation omitted)). Accordingly, the written description requirement is satisfied for the explicit DNA sequences that are recited in the present specification, *e.g.* SEQ ID NO:3, SEQ ID NO:3 containing the recited variations, and fragments of those sequences. Reconsideration and withdrawal of the present rejection is respectfully requested.

During the telephonic interview of January 12, 2005, the Examiner raised concerns that the phrase “fragments of SEQ ID NO:3” could include fragments of DNA that are 1-5 nucleotides long and that would be found in numerous other DNA sequences. To address that concern of the Examiner, Applicants have included a limitation where the fragments of SEQ ID NO:3 are at least twenty nucleotides in size. That amendment is fully supported by the present specification in that each of the fragments of SEQ ID NO:3 is explicitly recited in the present application. Under the standard expressed in *Lilly* and cited above, the written description is *per se* satisfied for that subject material.

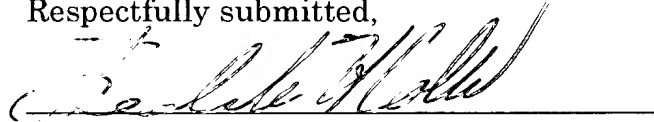
The Examiner also rejects Claims 18 and 20 under 35 U.S.C. § 112, ¶1 because while the specification is enabling for a host cell transformed with an expression vector, it is alleged to not enable any person skilled in the art to work with human or transgenic animals comprising SEQ ID NO:3. Applicants have amended Claims 18 and 20 to recite host cells, as opposed to expression systems. It is respectfully submitted that this amendment addresses the rejection by the

Examiner. Reconsideration and withdrawal of the present rejection is respectfully requested.

In view of the amendments to the claims and the remarks presented herein, it is respectfully submitted that the present application is in condition for final allowance and notice to such effect is requested. If the Examiner believes that additional issues need to be resolved before this application can be passed to issue, the undersigned invites the Examiner to contact him at the telephone number provided below.

Dated: February 22, 2005

Respectfully submitted,

A handwritten signature in dark ink, appearing to read "Frederick H. Colen", is written over a horizontal line.

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